THE HONORABLE JOHN C. COUGHENOUR 1 2 3 4 5 6 UNITED STATES DISTRICT COURT 7 WESTERN DISTRICT OF WASHINGTON AT SEATTLE 8 9 DAVID DEARINGER and GANNA CASE NO. C21-0060-JCC DEARINGER, 10 **ORDER** Plaintiffs, 11 12 v. 13 ELI LILLY AND COMPANY, 14 Defendant. 15 16 This matter comes before the Court on Plaintiffs' motion to amend their complaint (Dkt. 17 No. 65), Defendant's motion for summary judgment (Dkt. No. 59), and Defendant's motion to 18 seal (Dkt. No. 73). Having thoroughly considered the briefing and the relevant record, and 19 finding oral argument unnecessary, the Court hereby DENIES the motion to amend (Dkt. No. 20

65), GRANTS in part and DENIES in part the motion for summary judgment (Dkt. No 59), and GRANTS the motion to seal (Dkt. No. 73) for the reasons explained below.

### **BACKGROUND** I.

Plaintiffs allege in a Second Amended Complaint ("SAC") (Dkt. No. 37) that in 2018 Plaintiff David Dearinger suffered an intracranial brain hemorrhage, i.e., a stroke, resulting in the permanent loss of "sensory and motor function of the left side of his body." (Id. at 2–3.) The

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SAC contends that Defendant's prescription erectile dysfunction drug Cialis was the cause. [Id.] Accordingly, it asserts Washington's Product Liability Act ("WPLA") claims, along with fraudulent concealment and loss of consortium. (See generally id.) The SAC is the result of a long and winding road.

Plaintiffs brought the case in early 2021. At the time, they sought to file their complaint in forma pauperis ("IFP"). (See Dkt. No. 1.) The proposed complaint alleged Mr. Dearinger's stroke was, in fact, caused by Cialis and that Defendant failed to adequately warn Mr. Dearinger of this risk. (See generally Dkt. No. 1.) The associated claims were for negligence and loss of consortium. (Id.) The Court granted their IFP application, (Dkt. No. 4), but it declined to issue summons and dismissed the complaint without prejudice for failure to state a claim. (See Dkt. No. 9 at 1–2.) At the same time, the Court provided Plaintiffs leave to amend, suggesting they replead their allegations, but in support of a WPLA action. (Id.)<sup>2</sup>

Shortly thereafter, Plaintiffs filed their First Amended Complaint ("FAC") (Dkt. No. 10). It contained similar factual allegations as the last, but sought WPLA relief, along with a claim for loss of consortium. (*See id.* at 7–12.) On this basis, the Court issued summons. (*See* Dkt. No. 11.) Defendant then moved to dismiss. (*See generally* Dkt. No. 14.) It argued, in part, that Plaintiffs' failure to warn claim(s) failed as a matter of law, based on the learned intermediary doctrine. (*See id.* at 5–14.)<sup>3</sup> In response, Plaintiffs argued the doctrine should be modified for prescription

<sup>&</sup>lt;sup>1</sup> In a prior complaint, Plaintiffs alleged that the hemorrhage was, in fact, caused by Mr. Dearinger's ingestion of Cialis. (*See* Dkt. No. 10 at 4.) Whereas the SAC does not contain this explicit allegation. (*See generally* Dkt. No. 37.) Instead, it frames the issue primarily as one of proximate cause. (*See, e.g., id.* at 10–16.) Nevertheless, based on the allegations and legal conclusions contained throughout the SAC, the Court infers Plaintiffs maintain their contention that Mr. Dearinger's hemorrhage was, in fact, caused by Cialis. *See Blaisdell v. Frappiea*, 729 F.3d 1237, 1241 (9th Cir. 2013) (discussing the Court's "obligation to give a liberal construction to the filings of *pro se* litigants.").

<sup>&</sup>lt;sup>2</sup> The Court provided Plaintiffs this solicitude in light of their *pro se* status. *See Hughes v. Rowe*, 449 U.S. 5, 9 (1980).

<sup>&</sup>lt;sup>3</sup> According to the doctrine, so long as a prescription drug maker adequately warned a prescribing physician of the drug's risks, it had no duty to directly warn the patient, reserving

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drugs, like Cialis, if producers directly market them to consumers. (See Dkt. No. 20.) Lacking controlling authority for this proposition, Plaintiffs asked the Court to certify the question to the Washington Supreme Court. (Id.) The Court did just that and stayed consideration of Defendant's motion. (See Dkt. No. 28.)

In a June 2022 unanimous decision, the Washington Supreme Court confirmed that prescription medication marketed directly to consumers remained subject to the learned intermediary doctrine. Dearinger v. Eli Lilly and Co., 510 P.3d 326, 335 (Wash. 2022). According to that court, this is because all prescription drugs (regardless of how they are marketed) are complex and carry significant risks. *Id.* at 334. Only a prescribing physician can give "tailored warnings to patients . . . based on that patient's medical history and needs." Id.

Following this decision, this Court lifted the stay on Defendant's motion to dismiss, and then granted the motion. (See Dkt. No. 35 at 3-4.) It did so because the FAC failed to allege that Mr. Dearinger's prescribing physician would have acted differently if Cialis contained a different warning regarding the risk of stroke. (See generally Dkt. No. 10.) Nevertheless, the Court again granted Plaintiffs leave to amend, providing them yet another opportunity to adequately plead their claims before the case would proceed to discovery. (Dkt. No. 35 at 6.)

In July 2022 Plaintiffs then filed the SAC (Dkt. No. 37). This time, they alleged that "[a]n adequate warning of the risk of [stroke resulting from an intracranial hemorrhage] would have altered the prescribing physician's decision to prescribe Cialis." (Dkt. No. 37 at 12–15.) With this allegation, a key component of their legal theory, a failure to warn, was now adequately pleaded, and the Court allowed the case to proceed to discovery. (See Dkt. No. 48.)

With discovery ongoing, <sup>4</sup> Defendant now moves for summary judgment. (See Dkt. No. 59 at 15–24.) Plaintiffs oppose, (see Dkt. No. 67), and separately ask for leave to amend, (see generally Dkt. No. 65; see also Dkt. No. 65-1 at 2 (proposed Third Amended Complaint)).

this duty to the "learned intermediary." See Taylor v. Intuitive Surgical, Inc., 389 P.3d 517, 524 (Wash. 2017).

<sup>&</sup>lt;sup>4</sup> The cut-off date is February 2, 2024. (See Dkt. No. 48.)

# II. DISCUSSION

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### A. Motion to Amend

A court should "freely give leave to amend when justice so requires." Fed. R. Civ. P. 15(a)(2). In determining whether to do so, the Court considers "the presence or absence of undue delay, bad faith, dilatory motive, repeated failure to cure deficiencies . . . , undue prejudice to the opposing party[,] and futility of the proposed amendment." *Kroessler v. CVS Health Corp.*, 977 F.3d 803, 814–15 (9th Cir. 2020).

Defendant argues the proposed amendment is prejudicial and untimely. (*See* Dkt. No. 71 at 8, 14.) As to prejudice, Defendant relies on a need for additional discovery. (Dkt. No. 71 at 8–10.) Indeed, this can support a prejudice finding. *See AmerisourceBergen Corp. v. Dialysist West, Inc.*, 465 F.3d 946, 960 (9th Cir. 2006). But only if compelling reasons counsel against extending the discovery cut-off and/or trial date(s). And Defendant fails to explain how or why that is so here. (*See generally* Dkt. No. 71.) As to timeliness, Plaintiffs make vague references to newly obtained information, and assert they could not have discovered it earlier. (*See generally* Dkt. No. 65.) But their briefing lacks the specificity necessary to support their request for leave to amend. *See AmerisourceBergen Corp*, 464 F.3d at 953. Nevertheless, "delay alone . . . is an insufficient ground for denial of leave to amend. *U.S. v. Webb*, 655 F.2d 977, 980 (9th Cir. 1981). So these factors, on a combined basis, appear neutral.

But given the futility of Plaintiffs' proposed amendment, the Court declines Plaintiffs' request. *See Sweaney v. Ada County*, 119 F.3d 1385, 1393 (9th Cir. 1997). This is because the newly proposed claim(s) fail to relate back to those alleged in the original complaint, and without benefit of this provision, the proposed additional claim(s) are now time-barred. (*See* Dkt. No. 71 at 11.)

A pleading amendment relates back to the date of the original pleading when it "asserts a claim or defense that arose out of the conduct, transaction, or occurrence set out—or attempted to be set out—in the original pleading." Fed. R. Civ. P. 15(c)(1)(B). "Claims arise out of the

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same conduct, transaction, or occurrence if they share a common core of operative facts such that the plaintiff will rely on the same evidence to prove each claim." Williams v. Boeing Co., 517 F.3d 1120, 1133 (9th Cir. 2008). When a plaintiff seeks to amend a complaint to state a new claim against a defendant, "the court compares the original complaint with the amended complaint and decides whether the claim to be added will likely be proved by the 'same kind of evidence' offered in support of the original pleading." Percy v. S.F. General Hosp., 841 F.2d 975, 978 (9th Cir. 1988).

Plaintiff's proposed amendment relates to a July 2017 retinal detachment. Other than the alleged cause in fact—Mr. Dearinger's use of Cialis—this allegation shares no common core of facts with the 2018 stroke included in the SAC. (Compare Dkt. No. 65-1 at 14–17, with Dkt. No. 37 at 11–15.) Nor are they temporally related. Therefore, there is no basis to relate back the newly proposed claim(s) to the existing ones. And without an application of these rules, Plaintiff's new claims are time-barred. Any injury associated with the alleged retinal detachment occurred more than six years ago. (See Dkt. No. 65-1 at 14-17.) Yet the statute of limitations for WPLA claims is three years. RCW 7.72.060(3). This period began to run when Plaintiffs, through the "exercise of due diligence should have discovered the harm and its cause." Id. While Plaintiffs now contend that they only recently discovered the connection between the Mr. Dearinger's use of Cialis and his risk of retinal detachment, they fail to describe, with any specificity, why. (See generally Dkt. Nos. 65, 77, 82.)<sup>5</sup>

Accordingly, the Court DENIES Plaintiffs' motion for leave to amend (Dkt. No. 65).

# **B.** Motion for Summary Judgment

Defendant seeks summary judgment on all claims, arguing that, without any evidence supporting proximate cause, Plaintiffs cannot support their WPLA claims, and the remaining claims fail as a matter of law. (See Dkt. No. 59 at 10-24.) "The court shall grant summary

<sup>&</sup>lt;sup>5</sup> Defendant asks to strike the last submission (Dkt. No. 82) as untimely. (See Dkt. No. 83.) Because it ultimately is of no help to Plaintiffs, the Court declines that request.

judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In making such a determination, the Court must view the facts in the light most favorable to the nonmoving party and draw justifiable inferences in that party's favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). Ultimately, summary judgment is appropriate against a party who "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

In moving for summary judgment on Counts 1–3 of the SAC, Defendant relies primarily on testimony from two key individuals: Mr. Dearinger and Earl Bardin, M.D. (Dkt. No. 59.)

According to Mr. Dearinger, the Cialis dose at issue was, in fact, prescribed by Dr. Bardin. (Dkt. No. 60-5 at 6-7, 60-7 at 8.) And Dr. Bardin testified that (a) he was aware of Cialis's risk of

According to Mr. Dearinger, the Cialis dose at issue was, in fact, prescribed by Dr. Bardin. (Dkt. No. 60-5 at 6–7, 60-7 at 8.) And Dr. Bardin testified that (a) he was aware of Cialis's risk of hemorrhagic strokes and (b) even if he had received a stronger warning of the risk(s), *such as the one which Plaintiffs later suggest is adequate*, Dr. Bardin would not have "changed [his] decision to prescribe Cialis [to Mr. Dearinger]." (Dkt. Nos. 60-1 at 17, 26, 27; 60-7 at 15.)

Plaintiffs fail to provide any evidence rebutting this testimony. (*See generally* Dkt. No. 67.) Instead, they cast aspersions on Dr. Bardin's judgment and professional competence. (*See id.* at 9–11.) This is irrelevant to the case at hand, which is against Eli Lilly, not Dr. Bardin. Moreover, it is woefully inadequate to defeat a motion for summary judgment. In addition, the Court notes with some concern that this testimony *directly contradicts* the SAC's allegations. (*See* Dkt. No. 37 at 12–14.)

At least as it relates to claims involving a failure to warn of the risks of stroke, *i.e.*, Counts 2 and 3 of the SAC, the Court finds that Plaintiffs fail to establish a genuine issue of fact on the issue of proximate cause. *See Celotex Corp.*, 477 U.S. at 322; *see also* RCW 7.72.030(1)(b), (c) (describing a lack of "adequate warnings"). And without this, Plaintiffs cannot proceed to trial on these claims. Accordingly, summary judgment is GRANTED to

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Defendant on Counts 2 and 3 of the SAC. (See Dkt. No. 37 at 11–13 (citing RCW 7.72.030(1)(b), (c)).)

However, summary judgment is DENIED on Count 1, as that count is based on the WPLA's design defect provision(s), rather than a failure to warn. (*See id.* at 10–11 (citing RCW 7.72.030(1)(a), (3)).) And Defendant fails to meaningfully address this count in its motion. (*See generally* Dkt. No. 59.) Perhaps the same infirmity as to Counts 2 and 3 would apply to Count 1. But, if so, Defendant fails to indicate how. And the Court will not make Defendant's argument for it. *See Coto Settlement v. Eisenberg*, 593 F.3d 1031 (9th Cir. 2010).

Defendant also seeks summary judgment on Count 4, (Dkt. No 37 at 13–14), which asserts a claim for fraudulent concealment. (*See* Dkt. No. 59 at 21–22.) Defendant contends the claim fails as a matter of law for a number of reasons, including that it is barred by the WPLA. (*Id.* at 21–22.) The Court agrees. "The WPLA is the exclusive remedy [under Washington law] for product liability claims, including claims for inadequate warnings." *Taylor v. Intuitive Surgical, Inc.*, 389 P.3d 517, 523 (Wash. 2017). It supplants "all common law claims or actions based on harm caused by a product." *Macias v. Saberhagen Holdings, Inc.*, 282 P.3d 1069, 1073 (Wash. 2012). Accordingly summary judgment on Count 4 is GRANTED to Defendant.

In addition, Defendant seeks summary judgment on Count 5, (Dkt. No 37 at 16), which asserts a claim for loss of consortium. (*See* Dkt. No. 59 at 23.) But Defendant relies solely on its expectation that all predicate causes of action, *i.e.*, Counts 1–4 will be dismissed. (*Id.*) And for the reasons described above, Count 1 remains. So this argument is defective. Defendant provides the Court with no other basis supporting summary judgment on Count 5. Perhaps there is a separate basis to dismiss this claim. But again, the Court will not make Defendant's argument for it. Accordingly, summary judgment is DENIED on Count 5.

## C. Motion to Seal

Finally, Defendant moves to maintain under seal an exhibit containing medical and business records. (Dkt. No. 73.) While the public has a common law right to inspect and copy

public records, including those from judicial proceedings, these rights are not absolute. They 2 must yield when (1) sealing a document serves a compelling interest, (2) that is substantially 3 likely to be harmed if the document is not sealed, and (3) there are no less restrictive alternatives for protecting the interest. See United States v. Doe, 870 F.3d 991, 998 (9th Cir. 2017). Given the 5 nature of the information contained in the exhibits, these criteria are met here. Accordingly, 6 Defendant's motion to seal (Dkt. No. 73) is GRANTED. 7 III. **CONCLUSION** 8 For the foregoing reasons, the Court DENIES Plaintiffs' motion to amend (Dkt. No. 65), 9 GRANTS in part and DENIES in part Defendant's motion for summary judgment (Dkt. No 59), 10 and GRANTS Defendant's motion to seal (Dkt. No. 73) and ORDERS that Counts 2, 3, and 4 of 11 the SAC be DISMISSED with prejudice. 12 13 DATED this 18th day of December 2023. 14 15 16 John C. Coughenour 17 18

UNITED STATES DISTRICT JUDGE

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